

CONVENTIONAL IMPLICATURE IN PATIENT PACKAGE INSERTS

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Abstract

The study aims to investigate the legal aspects and the informative aspects, especially the conventional implicature of patient package inserts. Eighty five patient package inserts were collected from licensed drugstores in Surakarta and the surroundings from February 1, 2013 to February 15, 2013 to be qualitative content analyzed. It was found that out of eighty five inserts, seventy four (87 percents) gave explanation in Indonesian only; eight package inserts (9.4 percents) had English and Indonesian translations; and three (3.6 percents) had English texts only. It seems that most of the pharmaceutical companies do not think original leaflets important for drug users or public readers. The companies focus more on legal aspects than on good benefit that might be gained by attaching the original ones. Without original brochures, it is not known whether the translation meet the Readability Guideline expectations: faithful translation, understandable and patient-friendly. Eight package brochures having English and Indonesian translation were discussed. Three of them contained sentences with inference markers of conventional implicature. The inference markers were: *even*, *therefore* and *but*; their conventional implicature were explained by way of the drugs mechanisms and metabolisms in human body. The scarcity of conventional implicature indicated by only three words (*even*, *therefore* and *but*) or three sentences among about eight times five hundred words or around four hundred sentences could be an indication of appreciable efforts of the English writers to meet understandable and patient-friendly information. They seemed to avoid conventional implicature that might be understood differently by many drug users or public readers.

Key words: legal and informative aspects, readability, patient-friendly.

I. INTRODUCTION

It is becoming clearer every day that translation of medical texts is a very serious and full of responsibility activity, yet it represents an interesting and rich area for translation studies. In the present paper the focus is on the conventional implicature in the text with a genre of patient package inserts. This textual genre is mainly characterized by two essential aspects: (1) the legal aspects and (2) the informative aspects. Both aspects influence the pragmatic and textual features used in this genre (Herget and Alegre, 2010:2).

The legal aspect of patient package insert of drugs distributed in Indonesia is under controlled by Badan Pengawasan Obat dan Makanan Republik Indonesia (BPOM RI). A model of package insert is released by the government authorized body and must be followed by the pharmaceutical companies. The package inserts are structured in the following sections: (1) introduction consisting of name of medicine, active substance, strength and pharmaceutical form; (2) description of the medicine and therapeutic indications; (3) warnings and precautions; (4) instructions; (5) description of side effects; (6) description of storage conditions and (7) further information (BPOM, 2011; Herget and Alegre, 2010:3).

The informative aspect of package insert is predominantly functioning to give information to readers or users about the drugs. It also has additional functions such as instruction, warning, and recommendation. The importance of the package insert as a text genre has often been underlined in the literature, both because of the implication of its readability for people's health and a common genre (Cachiani, 2006:28). The package inserts are public consultation documents, and the correct use of drugs depends on the understanding of the package insert. Misunderstanding may have serious consequences, as we are dealing with human health (Herget and Alegre, 2010:1). Following Löning's model (Löning, 1981; *cit.* Herget and Alegre, 2010:2) of classification of medical discourse, which differentiates four levels according to the degree of specialization among the communication partners, package inserts are situated on level 3: communication between professional and layperson. The asymmetry of the communication and the great diversity and background of readers account for some of the style characteristics of the genre: the use of understandable words, which would be as common as

possible; the need to introduce explanations in the text; the consistency of the text structure with clear headings and the heterogeneous readership. Therefore, the contents should be presented in a conventionalized form, be as specific as possible and exclude ambiguity (BPOM, 2011:4; Herget and Alegre, 2010:6). As in every communication or interaction implicature always exists, it is interesting to investigate portions of implicature especially conventional implicature in package inserts. Logically, conventional implicature should be avoided as to minimize variations of understanding among drug users or readers and enhance understandability and patient-friendliness of patient package inserts.

This study investigates the existence of conventional implicature in the proportions of patient package inserts having English and Indonesian language translation.

II. METHODS

The study is conducted using qualitative content analysis method. The first part of the investigation starts with collecting patient package inserts from licensed drugstores in Surakarta and the surroundings from February 1st to 15th, 2013. The package inserts are filed in alphabetical order, then grouped according to the written language available: Indonesian only, English only and both. The proportions of the groups are calculated and expressed in percentage.

The second part of the study is reached by choosing and analyzing the package inserts in Indonesian language and its translation in English. The analysis used is the relational analysis is done by finding sentences using words indicating conventional implicature and explaining the meaning and role of the indicators.

III. FINDING AND DISCUSSION

Findings of the first part show that out of eighty five patient package inserts: seventy four (87 percents) give only explanation in Indonesian; eight package inserts (9.4 percents) have English and Indonesian translation; and three (3.6 percents) have English texts only (data available on request).

It is revealed that most of the patient package inserts (87 percents) are written in Indonesian. This is a consequence of the regulation produced by the Badan Pengawas Obat dan

Makanan Republik Indonesia (2011:4) which states that the product information for the patients should be written in simple and easy Indonesian. It must be remembered that this kind of communication is a one-way communication which does not allow individual asking the competent parties (Herget and Alegre, 2010:2). Following to Löning's model (Löning, 1981 *cit* Herget and Alegre, 2010:2-3) of medical discourse, which differentiates four main levels according to the degree of specialization among the communication partners and the aim of the text; package inserts are situated on level 3: communication between professional and layperson.

Table 1. Löning's model of medical discourse (adapted from Löning, *cit.* Herget and Alegre, 2010:2-3)

	Level 1: Scientific texts	Level 2: Instruction	Level 3: Education	Level 4: Popular scientific texts
Communication partners	Professional- Professional (Doctor-Doctor)	Professional- Half professional student/health professional	Professional- Layperson	Non- professional- Layperson
Aim	Transfer of current specialized knowledge	Transfer of basic knowledge	Education and practical instruction	Arouse interest and turn problems public

This regulation is beneficial to most Indonesian patients who cannot read English or other foreign languages. By reading the drug indications and instructions how to use it, mistakes and negative effects can be avoided. The Indonesian pharmaceutical companies also gain benefits as to save cost of printing the product information. From the translation view, especially medical translation, a proper translation must have a qualified translator or translators, in this case a linguist and a pharmacist or a medical doctor (Ruuskanen, 1994:300). In addition, the result should be evaluated for its equivalence, accuracy, readability and acceptability (Nababan, 2008:83-86; Leonardi, 2000:1). It is not declared if these requirements are fulfilled. Without underestimating the users of the drugs and publics, it should be realized that more and more

Indonesians understand foreign languages, including English as the *lingua franca* in scientific fields and medical knowledge (Berghammer, 2008:213). Relations, friends and publics should be involved in improving the proper use of drugs, strengthening the upgrading of knowledge and skill in choosing drugs for medical staffs by the Health Department of Republic of Indonesia (2008:11). BPOM RI may follow the European Commission (2009) in elaborating 'Readability Guidelines' and 'Readability Testing' (Andriensen, 2005:42-44) for patient information leaflets. The guidelines are written in detail, i.e. including syntax and style of sentences used.

Only 9.4 percents of patient package inserts have English and Indonesian translation. This is a highly appreciable effort by the pharmaceutical companies and hopefully followed by other companies. It is also expected that translation conducted following sound procedures. This portion is the core part of the study on conventional implicature. The least part, 3.4 percents of inserts do not have Indonesian translation. These drugs might be classified as imported drugs which cannot be produced in Indonesia or orphan drugs - drugs for rare diseases (BPOM, 2011:15-17). This portion is not discussed further.

The second part of the study aims to analyze conventional implicature in patient package inserts having English and Indonesian translation. Conventional implicature is a part of pragmatics study, so it is natural to look at the position of conventional implicature in pragmatics. In the early 1980s, when it first became common to discuss pragmatics in general textbooks on linguistics, the most common definitions of pragmatics were: meaning in use or meaning in context. Although these definitions are accurate enough and perfectly adequate as a starting point, they are too general - for example there are aspects of semantics, particularly semantics of the type developed since the late 1980s, which could well come under the headings of meaning in use or meaning in context (Thomas, 2005:1-2). Another definition is given by Verschueren (1999:1): pragmatics is the study of language use or the study of linguistic phenomena from the point of view of their usage properties and processes. Thomas (2005:22) summarizes the definition of pragmatics as meaning of interaction. Pragmatics covers some perspectives or facets as speech act theory, indirectness, theories of politeness, the constructions of meaning, felicity conditions, cooperative principle, conversational maxims, relevance, phatic tokens, deixis and implicature (Thomas, 2005:vii-xii). Mey (1993:vi-vii) and Verschueren



(1999:viii) describe micropragmatics and macropragmatics as divisions of pragmatics. In the above classifications, conventional implicature belongs to implicature in micropragmatics.

The word implicature is derived from the verb 'to imply', as its cognate 'implication'. Etymologically, 'to imply' means 'to fold something into something else' from the Latin verb *plicare* 'to fold'; hence, that which is implied, is 'folded in', and has to be 'unfolded' in order to be understood (Mey, 1993:99). The technical term 'implicature' was introduced by Paul Grice to cover a variety of non-explicit meanings, such as suggestions, implications and the like; some are 'conventional', i.e. attached conventionally to the linguistic forms; others are 'conversational' (Verschueren, 1999:30). They have in common the property that they both convey an additional level of meaning, beyond the semantic meaning of the words uttered. They differ in that in the case of conventional implicature the same implicature is always conveyed, regardless of context, whereas in the case of conversational implicature, what is implied varies according to the context of utterance (Thomas, 1995:57). If Austin (1962:39-41) made distinction between what speakers say and what they mean, Grice (1967, *cit.* Thomas, 1995:56) attempted at explaining how a hearer gets from what is meant, from the level of expressed meaning to the level of implied meaning.

There are comparatively few examples of conventional implicatures; Levinson (1983:127) lists four: *but*, *even*, *therefore* and *yet*. To these Thomas (1995:57) added some uses of *for*, as in: *She plays chess well, for a girl*. The implicature of this sentence is: that chess is commonly played by men.

An example of *but* is as follows:

... she was cursed with a stammer, unmarried but far from stupid.

Notice that although it is not actually asserted that unmarried people (or, perhaps, people who stammer) are stupid, the word *but* definitely implies that this is the case. The word *but* carries the implicature that what follows will run counter to expectation - this sense of the word *but* always carries this implicature, regardless of the context in which it occurs (Thomas, 1999:57).

As for *even*, the example is:

Even John came to the party.

It bears that of the people who came to the party, John was the least likely to come (Karttunen and Peters, 1979:3).

Therefore is the only one example of conventional implicature by Grice (1975 in Potts, 2007:1-2):

He is an Englishman; he is, *therefore*, brave.

The conventional implicature here is attributed to the presence of the lexical item *therefore* which conventionally implicates that the man's being brave follows from his being an Englishman.

The example of *yet* is found in the following sentence:

Dennis isn't here *yet*.

The speaker hopes that Dennis is already here, and the truth will come true (Yule, 2006:78).

The above understanding will be used to analyze the status of conventional implicature in the patient package inserts. As stated before, there are only eight leaflets have English and the Indonesian translation. The English texts of these brochures were read carefully to identify inference markers of conventional implicature. Out of eight inserts, three were found to have *even*, *therefore* and *but* as inference markers of conventional implicature.

In the brochure of *Captopril* drug (*Captopril* is the generic name of the drug, therefore it is ethical to mention its full name), at the Side Effects part, the second paragraph from the bottom, is stated as follows:

Loss of taste alteration, that usually occur in the first 3 months and will disappear even drug administration continued.

The inference marker here is: *even*. The conventional implicature of this statement is: the loss of taste alteration, that usually occurs in the first three months as the side effect of the drug caused by the accumulation of the drug metabolites will disappear without stopping taking the drug.



Side effects usually remain effective as the drug administration continued and it is advised to stop or reduce the dosage of the drug (Braunwald, *et al.* 1987:1244).

The second package leaflet examined is of Gtc® (the trade name of the drug is abbreviated as it is not ethical to write its full name). At the Warnings and Precautions part, the last paragraph says:

*Gtc may disturb the absorption of tetracycline or cimetidine, **therefore** those drugs must be given 2 hours after antacid administration.*

The inference marker found is: *therefore*. The conventional implicature of this statement is: the absorption of tetracycline and cimetidine by stomach will not be optimal if they are administered before two hours after taking Gtc®. One of the reasons of this phenomenon is the alteration of the acidity of stomach caused by Gtc® lasts for at least two hours. During this time, tetracycline and cimetidine will not be absorbed properly as they need certain specific acidity of the stomach to be absorbed optimally (Braunwald, *et al.* 1987:1033-1034).

The last package insert studied is of the Rndn® (Ethics prohibit writing full trade name of the drug). At the second paragraph of Drug Interactions Section, is written as follows:

*Digoxin: Diclofenac has been reported to increase plasma concentration of digoxin, **but** no clinical sign of overdose have been encountered.*

The inference marker of the sentence is: *but*. The conventional implicature of this sentence is: if digoxin is administered together with diclofenac, diclofenac will inhibit the excretion of digoxin out of the body which make digoxin concentration in plasma of the blood remains high. Higher concentration than expected after clearance time, or overdose of digoxin in plasma will give clinical signs, *i.e.* disturbance of cardiac/heart rhythm (Braunwald, *et al.* 1987:911). In contrast, this clinical sign never happens.

V. CONCLUSION

Eighty five patient package inserts were collected from licensed drugstores in Surakarta and the surroundings from February 1, 2013 to February 15, 2013 to be content analyzed

qualitatively to reveal its legal aspects and its pragmatics point of view especially its conventional implicature.

The first step of the study was filing the leaflets alphabetically, then grouping them according to the languages used in the brochures. It was found that out of eighty five inserts, seventy four (87 percents) gave only explanation in Indonesian; eight package inserts (9.4 percents) had English and Indonesian translations; and three (3.6 percents) had English texts only. It seems that most of the pharmaceutical companies do not think original leaflets important for drug users or public readers. The companies focus more to legal aspects than to good benefit that might be gained by attaching the original ones. Without original brochures, it is not known whether the translation meet the Readability Guideline expectations: faithful translation, understandable and patient-friendly. Three kinds of drug had no Indonesian translation, these drugs might belong to orphan drugs (drugs for rare diseases), or drugs that could not be produced in Indonesia. Eight package brochures had English and Indonesian translation, these brochures were discussed as materials for conventional implicature study.

Only three among eight package inserts contained sentences with inference markers of conventional implicature. The inference markers were: *even*, *therefore* and *but*; their conventional implicature were explained by way of the drugs mechanisms and metabolisms in human body. The scarcity of conventional implicature - three words (*even*, *therefore* and *but*) or three sentences among about eight times five hundred words or around four hundred sentences - could be an indication of appreciable efforts of the English writers of package leaflets to meet understandable and patient-friendly information. They seemed to avoid implicature that might be understood differently by many drug users or public readers.

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